IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

ANGELA PARKER, individually and as special administrator of the Estate of SAMANTHA PARKER, deceased.	)	
Plaintiff,	)	CASE NO: 17-CV-8550
vs.	)	Hon. Rebecca R. Pallmeyer
ZOLL SERVICES, LLC, a Nevada LLC d/b/a "ZOLL", ZOLL MEDICAL CORPORATION, a Massachusetts corporation d/b/a "ZOLL", ZOLL LIFEVEST HOLDINGS, LLC, a Nevada LLC d/b/a "ZOLL", ZOLL DATA SYSTEMS, LLC, a Delaware LLC d/b/a "ZOLL", ZOLL MANUFACTURING CORPORATION, a Nevada LLC d/b/a "ZOLL", RENAISSANCE AT MIDWAY, INC., an Illinois corporation, d/b/a RENAISSANCE AT MIDWAY,	)	
Defendants.	)	

SECOND AMENDED COMPLAINT

Plaintiff ANGELA PARKER, individually and as special administrator of the Estate of SAMANTHA PARKER, deceased, by and through her attorneys at GOLDBERG & GOLDBERG, and complaining of Defendants ZOLL SERVICES, LLC d/b/a "ZOLL", ZOLL MEDICAL CORPORATION d/b/a "ZOLL", ZOLL LIFEVEST HOLDINGS, LLC d/b/a "ZOLL", ZOLL DATA SYSTEMS, LLC d/b/a "ZOLL", ZOLL MANUFACTURING CORPORATION d/b/a "ZOLL", and RENAISSANCE AT MIDWAY, INC and in regard to SAMANTHA PARKER allege as follows:

SUMMARY OF ACTION

1. This matter is the result of the failure of a ZOLL LifeVest 4000. The LifeVest is a wearable defibrillator that is marketed as a treatment option for patients at risk for sudden cardiac arrest (SCA).

2. The LifeVest was programmed to provide a therapeutic shock if SAMANTHA PARKER experienced ventricular tachycardia ("V-tach") or ventricular fibrillation ("V-fib"). V-tach and/or V-fib will be referred to as a "defibrillation event."

3. On October 16, 2015, twenty-five year old SAMANTHA PARKER, plaintiff's decedent, was prescribed a ZOLL LifeVest by DR. AMER HUSSEINI. The ZOLL LifeVest was delivered to SAMANTHA PARKER at RENAISSANCE AT MIDWAY, INC. at 4437 S. Cicero Ave., Chicago, Cook County, Illinois, in the evening of October 16, 2015, by SUSAN O'MARA, a ZOLL Patient Services Representative ("PSR") and ZOLL agent and employee.

4. One day later on October 17, 2015, at approximately 20:00, at the location of 2260 S. Cicero, Chicago, Cook County, Illinois, SAMANTHA PARKER encountered a defibrillation event. The LifeVest she wore failed to deliver a therapeutic shock for at least 19 minutes, resulting in SAMANTHA PARKER's subsequent death. The ZOLL LifeVest's failure to deliver a therapeutic shock treatment was the result of ZOLL's violation of Federal Law and resulting negligent manufacture of the LifeVest.

5. Plaintiff filed a complaint in the State of Illinois, Circuit Court of Cook County on October 11, 2017.

6. Plaintiff filed a First Amended Complaint on October 16, 2017.

7. Plaintiff now files a Second Amended Complaint from conduct, transactions, and occurrences set forth in the Original and First Amended Complaint.

PARTIES, JURISDICTION, AND VENUE

8. At all times relevant, the defendants ZOLL SERVICES, LLC, ZOLL MEDICAL CORPORATION, ZOLL LIFEVEST HOLDINGS, LLC, ZOLL DATA SYSTEMS, LLC, and ZOLL MANUFACTURING CORPORATION, were all acting in conjunction and manufacturing the ZOLL LifeVest under the trademark "ZOLL."

9. At all times relevant, ZOLL was an authorized corporation in Illinois under File Number 61720839 and ZOLL transacted significant business in Illinois

and maintained an office at 1827 Walden Office Square # 555, Schaumburg, Cook County, Illinois.

10. At all times relevant, defendant RENAISSANCE AT MIDWAY, INC., d/b/a RENAISSANCE AT MIDWAY, was engaged in the business of owning and operating a post-acute care center at 4437 S. Cicero Ave., Chicago, Cook County, Illinois.

11. At all times relevant, SAMANTHA PARKER, plaintiff's decedent, was twenty-five years old and resided at 4437 S. Cicero Ave., Chicago, Cook County, Illinois. SAMANTHA PARKER was the daughter of ANGELA PARKER. At the time of her death, SAMANTHA PARKER had five living siblings.

12. At all times relevant, ANGELA PARKER, plaintiff, resided in Chicago, Cook County, Illinois, and was the mother of SAMANTHA PARKER. ANGELA PARKER has authority to bring this action.

FACTUAL ALLEGATIONS

A. THE ZOLL LIFEVEST AND ZOLL'S MARKETING STATEMENTS

13. ZOLL designs, manufactures, and markets the LifeVest, which is a Class III medical device initially approved for sale in 2001 by the U.S. Food and Drug Administration ("FDA"). The LifeVest approved in 2001 was known as the LifeVest 2000. The LifeVest 2000 later became known as the LifeVest 3000 and is currently known as the LifeVest 4000. This lawsuit concerns the LifeVest 4000.

14. The LifeVest 4000 is a wearable defibrillator that is worn by patients at risk for sudden cardiac arrest ("SCA").

15. The LifeVest consists of two main components – a garment and a monitor. The garment, worn under the clothing, detects arrhythmias, and delivers treatment shocks. The monitor is worn around the waist or from a shoulder strap and continuously monitors the patient's heart.

16. A medical doctor prescribes the LifeVest. After the LifeVest is prescribed, ZOLL contracts and deals directly with the patient and the patient's insurance carrier to place the LifeVest with the patient. In short, ZOLL leases the LifeVest directly to the patient, but receives payment from the patient's insurance carrier for the patient's use of the LifeVest. Patients are obligated to pay ZOLL amounts that are not covered by primary or secondary insurance.

17. ZOLL provides marketing statements on its website to promote and convince physicians to prescribe and patients to use its LifeVest devices.

18. ZOLL markets, claims and reassures patients that the LifeVest allows them to "return to their activities of daily living, while having the peace of mind that they are protected from SCA." According to ZOLL, the LifeVest provides "constant monitoring, immediate protection, and offers peace of mind for patients."

19. ZOLL markets, claims, and reassures patients that "[i]f a life-threatening heart rhythm is detected, the device delivers a treatment shock to restore normal heart rhythm. The entire event, from detecting a life-threatening arrhythmia to automatically delivering a treatment shock, usually occurs in less than a minute."

20. ZOLL markets, claims, and reassures patients that if the patient experiences a life threatening heart rhythm, the LifeVest will detect the rhythm and will deliver a treatment shock to restore the normal heart rhythm. ZOLL claims that the entire event, from detecting a life threatening arrhythmia to the LifeVest automatically administering the treatment shock, usually occurs in less than a minute.

21. ZOLL markets, claims, and reassures patients that the "LifeVest requires no bystander intervention. The LifeVest protects patients when they are alone or sleeping. The LifeVest provides constant monitoring, immediate protection, and offers peace of mind for patients. In addition, the LifeVest offers peace of mind for family members who may worry about awaiting EMS personnel arrival or having to resuscitate a loved one themselves."

22. ZOLL markets, claims, and reassures patients that the LifeVest "has a **98 percent first treatment shock success rate** for resuscitating patients from SCA."

23. ZOLL states that "Timely defibrillation is the single **most** important factor in saving a SCA victim's life. A treatment shock **must** be delivered within a **few** minutes after an event to be effective; with each passing minute, a patient's chances of survival drops 10 percent."

24. The ZOLL claims and statements alleged in paragraphs 17-23 are individually and collectively the "Marketing Statements."

B. THE SEPTEMBER 2014 FDA WARNING LETTER

25. From May 22, 2014, through June 20, 2014, the FDA inspected the ZOLL facility that manufactures and distributes the LifeVest devices, including the subject LifeVest 4000 ("FDA Inspection").

26. Subsequent to the FDA Inspection, the FDA issued a warning letter dated September 23, 2014. (Exhibit A - "Warning Letter").

27. The Warning Letter informed ZOLL that ZOLL's many violations of the Federal Food, Drug and Cosmetic Act rendered the LifeVest 4000 adulterated under section 501(h) of the act.

28. The Warning Letter informed ZOLL that LifeVest devices being manufactured and distributed are "**adulterated** within the meaning of Section 501(h)" of the Federal Food, Drug, and Cosmetic Act.

29. The Warning Letter informed ZOLL that the "LifeVest Wearable Defibrillator is **misbranded** under Section 502(t)(2) of the Act, 21 U.S.C. § 352(t)(2)..."

30. The FDA Inspection further found that "the methods used in, or the facilities or controls used for, their manufacture, processing, packing or installation are **not in conformity** with the current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) Regulation found at Title 21, Code of Federal Regulations (CFR), Part 820."

31. The Warning Letter further informed ZOLL that it was in violation of numerous Federal Food & Drug Quality System Regulations to ensure that finished devices will be safe and effective. 21 C.F.R. 820.1(a)(1). Federal regulations under part 820 were established and issued under authority of sections 501, 502, 510, 513, 514, 515, 518, 519, 520, 522, 701, 704, 801, 803 of the Federal Food, Drug, and Cosmetic Act. (21 U.S.C. 351, 352, 360, 360c, 360d, 360e, 360h, 360i, 360j, 360l, 371, 374, 381, 383).

32. The Warning Letter informed ZOLL that not all of the violations were included in the Warning Letter

33. The Warning Letter informed ZOLL that it violated 21 C.F.R. 820.100(b) by failing to document corrective and preventative actions. (Warning Letter, paragraph 1).

34. The Warning Letter informed ZOLL that it violated 21 C.F.R. 820.198(a) by failing thoroughly investigate, review, and evaluate complaints through ZOLL's Regulatory Affairs Office. (Warning Letter, paragraph 2).

35. The Warning Letter informed ZOLL that it violated 21 C.F.R. 820.30(g) by failing to adequately establish procedures for design validation and not adequate validating the LifeVest 4000 under actual or simulated use conditions. (Warning Letter, paragraph 3).

36. The Warning Letter informed ZOLL that it violated 21 C.F.R. 820.20(c) because the management with executive responsibility failed to review the suitability and effectiveness of the quality system at defined intervals, and with

sufficient frequency, according to established procedures. (Warning Letter, paragraph 4).

37. Importantly, neither the full FDA investigation nor the responses submitted by ZOLL are released to the public.

38. A close out letter, indicating that ZOLL had corrected the violations, was not issued to ZOLL until after SAMANTHA PARKER'S death.

C. PLACEMENT OF THE LIFEVEST, ZOLL'S MISREPRESENTATIONS, AND SUSAN O'MARA'S MISREPRESENTATIONS.

39. On October 16, 2015, and for approximately 6 weeks prior, SAMANTHA PARKER was a resident at defendant RENAISSANCE AT MIDWAY, INC's post-acute care center located at 4437 S. Cicero Avenue, Chicago, IL.

40. On or about October 16, 2015, DR. AMER HUSSEINI, M.D., prescribed the ZOLL LifeVest to SAMANTHA PARKER.

41. DR. MALKAN PATEL, M.D., SAMANTHA PARKER'S physician, was made aware of the prescription.

42. AMER HUSSEINI, M.D. ordered that employees of RENAISSANCE AT MIDWAY, INC. perform checks on SAMANTHA PARKER'S ZOLL LifeVest every shift to ensure the LifeVest was appropriately placed and functioning properly.

43. On October 16, 2015, SUSAN O'MARA provided the LifeVest to SAMANTHA PARKER.

44. At that time SUSAN O'MARA was a ZOLL Patient Services Representative, was an employee of ZOLL, was compensated by ZOLL, and was acting as an agent of ZOLL.

45. SUSAN O'MARA had SAMANTHA PARKER sign a contract with ZOLL.

46. The contract obligated SAMANTHA PARKER to pay for the lease of the LifeVest and services provided by ZOLL.

47. SUSAN O'MARA signed the same contract.

48. SUSAN O'MARA fit SAMANTHA PARKER for the LifeVest.

49. SUSAN O'MARA trained SAMANTHA PARKER in the use of the LifeVest.

50. The above training included, but was not limited to how to operate the response buttons, how to charge the batteries, how to change the garment, and how to connect the LifeVest device to the telephone for transmission of data.

51. SUSAN O'MARA provided written instructions to SAMANTHA PARKER on the safe and effective use of the LifeVest.

52. SUSAN O'MARA provided a Patient Manual to SAMANTHA PARKER.

53. SUSAN O'MARA provided a Patient Agreement to SAMANTHA PARKER.

54. SUSAN O'MARA represented to SAMANTHA PARKER that the LifeVest 4000 was a safe treatment option.

55. SUSAN O'MARA answered questions SAMANTHA PARKER had concerning the use and effectiveness of the LifeVest.

56. As an employee of ZOLL and patient service representative, SUSAN O'MARA was aware of the Warning Letter at the time she provided SAMANTHA PARKER with the LifeVest.

57. The LifeVest, which was placed directly on SAMANTHA PARKER by ZOLL's employee, SUSAN O'MARA, and was not modified or changed from the time it was placed into the stream of commerce by ZOLL.

D. SAMANTHA PARKER'S DEATH

58. On October 17, 2015, at approximately 14:39, KAMESHIA MOBLEY, R.N., an employee of RENAISSANCE AT MIDWAY, INC., performed a check on SAMANTHA PARKER and noted that the LifeVest was "in place" and "functioning well."

59. On October 17, 2015, at approximately 19:30, SAMANTHA PARKER obtained a Leave of Absence from RENAISSANCE AT MIDWAY, INC. SAMANTHA PARKER traveled to 2260 S. Cicero, Chicago, Cook County, Illinois.

60. At approximately 20:00 SAMANTHA PARKER experienced ventricular fibrillation ("V-fib").

61. The LifeVest detected the V-fib.

62. For at least 19 minutes, the LifeVest detected seven arrhythmias with a V-fib rhythm.

63. Despite detecting seven arrhythmias over the course of at least 19 minutes the LifeVest did not sound an alarm or administer a therapeutic electric shock.

64. The V-fib experienced by SAMANTHA PARKER constituted a defibrillation event.

65. The LifeVest should have delivered a therapeutic shock within a minute of the defibrillation event being detected by the LifeVest.

66. After at least 19 minutes of monitoring a defibrillation event, the LifeVest sounded an alarm and administered a therapeutic shock which converted SAMANTHA PARKER'S heart rhythm from V-fib to pulseless electrical activity ("PEA").

67. The delay caused irreversible damage to SAMANTHA PARKER'S heart and brain.

68. On October 17, 2015, at approximately 20:35, SAMANTHA PARKER was transported by ambulance to MacNeal Hospital. SAMANTHA PARKER coded and was resuscitated a number of times before eventually expiring on October 17, 2015 at 22:07.

69. SAMANTHA PARKER'S cause of death was determined to be dilated cardiomyopathy.

E. MANUFACTURING DEFECT WITH THE LIFEVEST

70. The LifeVest that ZOLL provided to SAMANTHA PARKER had a manufacturing defect, which caused the LifeVest to fail to properly detect and treat SAMANTHA PARKER'S defibrillation events.

71. The manufacturing defect was the result of ZOLL's failure to comply with relevant Federal Law in the manufacturing of the LifeVest as stated in the Warning Letter.

72. 21 CFR 820.100 required, but ZOLL failed to establish and maintain procedures for implementing corrective and preventive action with respect to the LifeVest devices, including the subject LifeVest. Specifically, ZOLL failed to, among other things, establish and maintain procedures for (1) analyzing processes, work operations, quality records, and other information to identify existing and potential causes of nonconforming product, (2) investigating the cause of nonconformities, (3) identifying appropriate actions needed to correct and prevent recurrence of nonconforming product, (4) verifying and validating that the appropriate actions to prevent and remedy nonconformities were effective, and (5) documenting the processes and actions discussed above.

73. 21 CFR 820.30(g) required, but ZOLL failed to validate the design of the LifeVest devices by failing, among other things, (1) to ensure that the devices conformed to defined user needs and intended uses, and (2) to test the devices under actual or simulated use conditions.

74. 21 CFR 820.20(c) required, but ZOLL's management failed to review the procedures it was required to, but did not implement to ensure that ZOLL's quality systems, which were severely lacking, satisfied the requirements of the current Good Manufacturing Practice (CGMP) requirements and of ZOLL's quality policy and objectives.

75. 21 CFR 820.198 required, but ZOLL failed to establish procedures for reviewing complaints relating to the LifeVest devices, including their failure to work, and consequently, failed to adequately evaluate and investigate problems with non-conforming devices.

76. The defects in the ZOLL LifeVest 4000 include but are not limited to (1) manufacturing defects in the diagnostic and detection software installed by ZOLL; (2) manufacturing defects in the treatment software installed by ZOLL; (3) manufacturing defects in the heart sensors, or electrodes, preventing accurate monitoring of heart rate; (4) manufacturing defects in the connector which connects the electrode belt to the monitor; (5) manufacturing defects in the vibration box which connects the heart sensors to the therapy pads; (6) manufacturing defects in the therapy pads.

77. ZOLL's failure to comply with Federal Law resulted the subject LifeVest being defective, preventing it from properly detecting and treating SAMANTHA PARKER'S defibrillation event.

COUNT 1 – ZOLL'S VIOLATION OF SECTION 3.1 OF THE ILLINOIS FOOD, DRUG AND COSMETIC ACT

NOW COMES the Plaintiff, ANGELA PARKER, Special Administrator, of the Estate of SAMANTHA PARKER, Deceased, by and through her attorneys, GOLDBERG & GOLDBERG, and complains of the Defendant, ZOLL, as follows:

1. Plaintiff incorporates introductory paragraphs 1-77 as set forth above.

2. The Illinois Food, Drug, and Cosmetic Act establishes regulations parallel to Federal requirements under the Federal Food, Drug, and Cosmetic Act.

3. Section 410 ILCS 620/3 of the Illinois Food, Drug, and Cosmetic Act states that Sections 3.1 through 3.21 and the causing thereof are prohibited in Illinois.

4. Section 3.1 of the Illinois Food, Drug, and Cosmetic Act prohibits the sale or delivery of any device that is **adulterated** or **misbranded**.

5. Section 3.1 is parallel to Federal Law because it does not create requirements different from or in addition to requirements imposed by Federal Law. See Raleigh v. Alcon Laboratories, Inc., 403 Ill.App.3d 863.

6. Defendant ZOLL violated Section 3.1 of the Illinois Food, Drug, and Cosmetic Act as determined by the F.D.A warning letter. The Warning Letter stated that the LifeVest was "**adulterated** within the meaning of Section 501(h) of the Act, 21 U.S.C. 351(h), in that the methods used in, or the facilities or controls used for, their manufacture, processing, packing, or installation are not in conformity with the current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) Regulation found at Title 21, Code of Federal Regulations (CFR), Part 820."

7. The Warning Letter further states that "LifeVest Wearable Defibrillator is **misbranded** under Section 502(t)(2) of the Act, 21 U.S.C. § 352(t)(2)..."

8. The Illinois Supreme Court determined Illinois Law provides a private right of action for violation of Section 3.1 of the Illinois Food, Drug and Cosmetic Act because (1) plaintiff is a member of the class for whose benefit the statute was enacted; (2) the plaintiff's injury and death is one the statute was designed to prevent; (3) plaintiff's right of action is consistent with the underlying purpose of the statute; and (4) a private right of action is necessary to provide an adequate remedy for defendant's violations. See Fisher v. Lexington Health Care, Inc., 188 Ill.2d 455 (1999).

9. SAMANTHA PARKER was a member of the class for whose benefit Section 3.1 was enacted.

10. SAMANTHA PARKER'S injury and death is one Section 3.1 was designed to prevent.

11. Plaintiff's right of action is consistent with the underlying purpose of Section 3.1.

12. A private right of action is necessary to provide Plaintiff an adequate remedy for Zoll's violations.

13. ZOLL's violation of Section 3.1 caused SAMANTHA PARKER to be exposed to and rely upon ZOLL's defective LifeVest instead of choosing alternative treatment options for her condition.

14. ZOLL's violation of Sections 3.1 directly or proximately caused or contributed to SAMANTHA PARKER'S injury and death.

15. As a result of SAMANTHA PARKER'S death, Plaintiff continues to suffer damages, including but not limited to damages for (1) loss of support and services, (2) loss of companionship and protection, (3) mental suffering, (4) medical and (5) funeral expense.

16. Additionally, as this claim is not based on strict product liability Plaintiff also seeks punitive damages for ZOLL's actions.

WHEREFORE, the Plaintiff, ANGELA PARKER, Special Administrator of the Estate of SAMANTHA PARKER, Deceased, demands judgment against the Defendant, ZOLL, in a dollar amount in excess of the jurisdictional limitation of this Court, and for such other and further amounts as the jury and the Court shall deem proper, plus the cost of this suit.

COUNT 2 – ZOLL'S VIOLATION OF SECTION 3.18 OF THE ILLINOIS FOOD, DRUG AND COSMETIC ACT

NOW COMES the Plaintiff, ANGELA PARKER, Special Administrator, of the Estate of SAMANTHA PARKER, Deceased, by and through her attorneys, GOLDBERG & GOLDBERG, and complains of the Defendant, ZOLL, as follows:

1. Plaintiff incorporates introductory paragraphs 1-77 as set forth above.

2. The Illinois Food, Drug, and Cosmetic Act establishes regulations parallel to Federal requirements under the Federal Food, Drug, and Cosmetic Act.

3. Section 410 ILCS 620/3 of the Illinois Food, Drug, and Cosmetic Act states that Sections 3.1 through 3.21 and the causing thereof are prohibited in Illinois.

4. Section 3.18 of the Illinois Food, Drug, and Cosmetic Act is titled "Failure to Comply with §§ 518, 519 or 520 of the Federal Act" and prohibits "The failure or refusal to (A) comply with any requirement prescribed under Section 518 or 520(g) of the Federal Act, or (B) furnish any notification or other material or information required by or under **Section 519** or 520(g) of the Federal Act. (2) With respect to any device, the submission of any report that is required by or under this Act that is false or misleading in any material respect."

5. Defendant ZOLL violated Section 3.18 of the Illinois Food, Drug, and Cosmetic Act as determined by the F.D.A warning letter. As stated in Warning Letter, "the LifeVest Wearable Defibrillator is **misbranded** under Section 502(t)(2) of the Act, 21 U.S.C. § 352(t)(2), in that [ZOLL] failed or refused to furnish material or information regarding the devices that is required by or under **Section 519** of the Act, 21 U.S.C. § 360i, and 21 CFR Part 803 - Medical Device Reporting...."

6. Therefore, by violating Section 519 of the Federal Act, Zoll violated Section 3.18 of the Illinois Food, Drug, and Cosmetic Act when it provided SAMANTHA PARKER the LifeVest in Illinois.

7. Section 3.18 is parallel to Federal Law because it does not create requirements different from or in addition to requirements imposed by Federal Law. See Raleigh v. Alcon Laboratories, Inc., 403 Ill.App.3d 863.

8. The Illinois Supreme Court determined Illinois Law provides a private right of action for violation of Section 3.18 of the Illinois Food, Drug and Cosmetic Act because (1) plaintiff is a member of the class for whose benefit the statute was enacted; (2) the plaintiff's injury and death is one the statute was designed to prevent; (3) plaintiff's right of action is consistent with the underlying purpose of the statute; and (4) a private right of action is necessary to provide an adequate remedy for defendant's violations. See Fisher v. Lexington Health Care, Inc., 188 Ill.2d 455 (1999).

9. SAMANTHA PARKER was a member of the class for whose benefit Section 3.18 was enacted.

10. SAMANTHA PARKER'S injury and death is one Section 3.18 was designed to prevent.

11. Plaintiff's right of action is consistent with the underlying purpose of Section 3.18.

12. A private right of action is necessary to provide Plaintiff an adequate remedy for Zoll's violations.

13. ZOLL's violation of Section 3.18 caused SAMANTHA PARKER to be exposed to and rely upon ZOLL's defective LifeVest instead of choosing alternative treatment options for her condition.

14. ZOLL's violation of Section 3.18 directly or proximately caused or contributed to SAMANTHA PARKER'S injury and death.

15. As a result of SAMANTHA PARKER'S death, Plaintiff continues to suffer damages, including but not limited to damages for (1) loss of support and services, (2) loss of companionship and protection, (3) mental suffering, (4) medical and (5) funeral expense.

16. Additionally, as this claim is not based on strict product liability Plaintiff also seeks punitive damages for ZOLL's actions.

WHEREFORE, the Plaintiff, ANGELA PARKER, Special Administrator of the Estate of SAMANTHA PARKER, Deceased, demands judgment against the

Defendant, ZOLL, in a dollar amount in excess of the jurisdictional limitation of this Court, and for such other and further amounts as the jury and the Court shall deem proper, plus the cost of this suit.

COUNT 3 – ZOLL'S VIOLATION OF SECTION 14(u) OF THE ILLINOIS FOOD, DRUG AND COSMETIC ACT

NOW COMES the Plaintiff, ANGELA PARKER, Special Administrator, of the Estate of SAMANTHA PARKER, Deceased, by and through her attorneys, GOLDBERG & GOLDBERG, and complains of the Defendant, ZOLL, as follows:

1. Plaintiff incorporates introductory paragraphs 1-77 as set forth above.

2. The Illinois Food, Drug, and Cosmetic Act establishes regulations parallel to Federal requirements under the Federal Food, Drug, and Cosmetic Act.

3. Section 410 ILCS 620/3 of the Illinois Food, Drug, and Cosmetic Act states that Sections 3.1 through 3.21 and the causing thereof are prohibited in Illinois.

4. Section 3.1 of the Illinois Food, Drug, and Cosmetic Act prohibits the sale or delivery of any device that is **adulterated** or misbranded.

5. 410 ILCS 620, Section 14 of the Illinois Food, Drug, and Cosmetic Act is titled "**Adulterated** Drug or Device" and subsection (u) states that a device is adulterated if "it is a device and there was a failure or refusal (1) to comply with any requirement prescribed under Section 518 of the Federal Act respecting the device, or (2) to furnish material required by or under Section 519 of the Federal Act respecting the device."

6. Defendant ZOLL violated Section 14(u) of the Illinois Food, Drug, and Cosmetic Act as determined by the F.D.A warning letter. As stated in Warning Letter, the LifeVest was "**adulterated** within the meaning of Section 501(h) of the Act, 21 U.S.C. § 351(h), in that the methods used in, or the facilities or controls used for, their manufacture, processing, packing, or installation are not in conformity with the current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) Regulation found at Title 21, Code of Federal Regulations (CFR), Part 820."

7. Section 14(u) is parallel to Federal Law because it does not create requirements different from or in addition to requirements imposed by Federal Law. See Raleigh v. Alcon Laboratories, Inc., 403 Ill.App.3d 863.

8. The Illinois Supreme Court determined Illinois Law provides a private right of action for violation of Section 14(u) of the Illinois Food, Drug and Cosmetic Act because (1) plaintiff is a member of the class for whose benefit the statute was

enacted; (2) the plaintiff's injury and death is one the statute was designed to prevent; (3) plaintiff's right of action is consistent with the underlying purpose of the statute; and (4) a private right of action is necessary to provide an adequate remedy for defendant's violations. See Fisher v. Lexington Health Care, Inc., 188 Ill.2d 455 (1999).

9. SAMANTHA PARKER was a member of the class for whose benefit Section 14(u) and was enacted.

10. SAMANTHA PARKER'S injury and death is one Section 14(u) was designed to prevent.

11. Plaintiff's right of action is consistent with the underlying purpose of Section 14(u)

12. A private right of action is necessary to provide Plaintiff an adequate remedy for Zoll's violations.

13. ZOLL's violation of Section 14(u) caused SAMANTHA PARKER to be exposed to and rely upon ZOLL's defective LifeVest instead of choosing alternative treatment options for her condition.

14. ZOLL's violation of Section 14(u) directly or proximately caused or contributed to SAMANTHA PARKER'S injury and death.

15. As a result of SAMANTHA PARKER'S death, Plaintiff continues to suffer damages, including but not limited to damages for (1) loss of support and services, (2) loss of companionship and protection, (3) mental suffering, (4) medical and (5) funeral expense.

16. Additionally, as this claim is not based on strict product liability Plaintiff also seeks punitive damages for ZOLL's actions.

WHEREFORE, the Plaintiff, ANGELA PARKER, Special Administrator of the Estate of SAMANTHA PARKER, Deceased, demands judgment against the Defendant, ZOLL, in a dollar amount in excess of the jurisdictional limitation of this Court, and for such other and further amounts as the jury and the Court shall deem proper, plus the cost of this suit.

COUNT 4 – ZOLL'S VIOLATION OF SECTION 15(u) OF THE ILLINOIS FOOD, DRUG AND COSMETIC ACT

NOW COMES the Plaintiff, ANGELA PARKER, Special Administrator, of the Estate of SAMANTHA PARKER, Deceased, by and through her attorneys, GOLDBERG & GOLDBERG, and complains of the Defendant, ZOLL, as follows:

1. Plaintiff incorporates introductory paragraphs 1-77 as set forth above.

2. The Illinois Food, Drug, and Cosmetic Act establishes regulations parallel to Federal requirements under the Federal Food, Drug, and Cosmetic Act.

3. Section 410 ILCS 620/3 of the Illinois Food, Drug, and Cosmetic Act states that Sections 3.1 through 3.21 and the causing thereof are prohibited in Illinois.

4. Section 3.1 of the Illinois Food, Drug, and Cosmetic Act prohibits the sale or delivery of any device that is adulterated or **misbranded**.

5. 410 ILCS 620, Section 15 of the Illinois Food, Drug, and Cosmetic Act is titled "**Misbranded Drug or Device**" and subsection (u) states that a device is misbranded if "it is a device and there was a failure or refusal (1) to comply with any requirement prescribed under Section 518 of the Federal Act respecting the device, or (2) to furnish material required by or under **Section 519 of the Federal Act** respecting the device."

6. Defendant ZOLL violated Section 15(u) of the Illinois Food, Drug, and Cosmetic Act as determined by the F.D.A warning letter. As stated in Warning Letter, the "LifeVest Wearable Defibrillator is **misbranded** under Section 502(t)(2) of the Act, 21 U.S.C. § 352(t)(2), in that your firm failed or refused to furnish material or information regarding the devices that is **required by or under Section 519 of the Act**, 21 U.S.C. § 360i, and 21 CFR Part 803 - Medical Device Reporting."

7. Section 15(u) is parallel to Federal Law because it does not create requirements different from or in addition to requirements imposed by Federal Law. See Raleigh v. Alcon Laboratories, Inc., 403 Ill.App.3d 863.

8. The Illinois Supreme Court determined Illinois Law provides a private right of action for violation of Section 15 of the Illinois Food, Drug and Cosmetic Act because (1) plaintiff is a member of the class for whose benefit the statute was enacted; (2) the plaintiff's injury and death is one the statute was designed to prevent; (3) plaintiff's right of action is consistent with the underlying purpose of the statute; and (4) a private right of action is necessary to provide an adequate remedy for defendant's violations. See Fisher v. Lexington Health Care, Inc., 188 Ill.2d 455 (1999).

9. SAMANTHA PARKER was a member of the class for whose benefit Section 15(u) and was enacted.

10. SAMANTHA PARKER'S injury and death is one Section 15(u) was designed to prevent.

11. Plaintiff's right of action is consistent with the underlying purpose of Section 15(u)

12. A private right of action is necessary to provide Plaintiff an adequate remedy for Zoll's violations.

13. ZOLL's violation of Section 15(u) caused SAMANTHA PARKER to be exposed to and rely upon ZOLL's defective LifeVest instead of choosing alternative treatment options for her condition.

14. ZOLL's violation of Section 15(u) directly or proximately caused or contributed to SAMANTHA PARKER'S injury and death.

15. As a result of SAMANTHA PARKER'S death, Plaintiff continues to suffer damages, including but not limited to damages for (1) loss of support and services, (2) loss of companionship and protection, (3) mental suffering, (4) medical and (5) funeral expense.

16. Additionally, as this claim is not based on strict product liability Plaintiff also seeks punitive damages for ZOLL's actions.

WHEREFORE, the Plaintiff, ANGELA PARKER, Special Administrator of the Estate of SAMANTHA PARKER, Deceased, demands judgment against the Defendant, ZOLL, in a dollar amount in excess of the jurisdictional limitation of this Court, and for such other and further amounts as the jury and the Court shall deem proper, plus the cost of this suit.

COUNT 5 –WRONGFUL DEATH – NEGLIGENCE PER SE FOR VIOLATION THE ILLINOIS FOOD, DRUG, AND COSMETIC ACT - AGAINST ZOLL

NOW COMES the Plaintiff, ANGELA PARKER, Special Administrator, of the Estate of SAMANTHA PARKER, Deceased, by and through her attorneys, GOLDBERG & GOLDBERG, and complains of the Defendant, ZOLL, and Defendant SUSAN O'MARA as follows:

1. Plaintiff incorporates introductory paragraphs 1-77 as set forth above.

2. On October 16, 2015, SUSAN O'MARA, provided the LifeVest to SAMANTHA PARKER at RENAISSANCE AT MIDWAY.

3. At that time SUSAN O'MARA was a ZOLL Patient Services Representative, was an employee of ZOLL, was compensated by ZOLL, was acting as an agent of ZOLL.

4. SUSAN O'MARA had SAMANTHA PARKER sign a contract with ZOLL.

5. The contract obligated SAMANTHA PARKER to pay for the services provided by ZOLL and to use the LifeVest.

6. SUSAN O'MARA, ZOLL's agent, signed the same contract.

7. ZOLL owed SAMANTHA PARKER a duty to provide a safe and legal medical device, in part, because of the contractually relationship established on that day.

8. At that time, there was in full force and effect The Illinois Food, Drug, and Cosmetic Act.

9. The Illinois Food, Drug, and Cosmetic Act establishes regulations parallel to Federal requirements under the Federal Food, Drug, and Cosmetic Act.

10. Section 410 ILCS 620/3 of the Illinois Food, Drug, and Cosmetic Act provided that Sections 3.1 through 3.21 and the causing thereof are prohibited in Illinois.

11. Section 3.1 of the Illinois Food, Drug, and Cosmetic Act prohibits the sale or delivery of any device that is adulterated or misbranded.

12. The Warning Letter states that the LifeVest is adulterated and misbranded according to Federal Law.

13. This made the LiveVest adulterated by Illinois according to 410 ILCS 620, Section 14(u) and Section 15(u).

14. The cause of the LifeVest being adulterated and misbranded was ZOLL's violation of Federal Law as outlined by the FDA's Warning Letter. As a result, claims of Negligence Per Se are not pre-empted by Federal Law. Bausch v. Stryker Corp., 630 F.3d 546, 550 (7th Cir. 2010).

15. By selling and providing SAMANTHA PARKER a misbranded and adulterated LifeVest on October 16, 2015 in the State of Illinois, ZOLL and its agent, SUSAN O'MARA violated the Illinois Food, Drug, and Cosmetic Act.

16. ZOLL's violation of the Illinois Food, Drug, and Cosmetic Act caused SAMANTHA PARKER to be exposed to and rely upon ZOLL's defective LifeVest instead of choosing alternative treatment options for her condition.

17. That as a direct and proximate result of ZOLL's violation of the Illinois Food, Drug, and Cosmetic Act the plaintiff's decedent, SAMANTHA PARKER, died on October 17, 2015, or soon thereafter, when her ZOLL LifeVest 4000 failed to provide a necessary electric shock therapy during a defibrillation event.

18. ZOLL's violation of the Illinois Food, Drug, and Cosmetic Act directly or proximately caused or contributed to SAMANTHA PARKER'S injury and death.

19. ZOLL's violation of the Illinois Food, Drug, and Cosmetic Act directly or proximately caused SAMANTHA PARKER to suffer from conscious pain and suffering.

20. That at all relevant times, there was in full force and effect in the State of Illinois, a certain Act, commonly known as the Wrongful Death Act, 740 ILCS 180/1-2 et seq., which provided in pertinent part as follows:

21. "Whenever the death of a person shall be caused by wrongful act, neglect or default, and the act, neglect or default is such as would, if death had ensued, have entitled the party injured to maintain an action and recover damages in respect thereof, then and in every such case the person who or company or corporation which would have been liable if death had not ensued, shall be liable to an action for damages, notwithstanding the death of the person injured and although the death shall have been caused under such circumstances as amount in law to felon. (740 ILCS 180/1)

22. Every such action shall be brought by and in the names of the personal representatives of such deceased person, and, except as otherwise hereinafter provided, the amount recovered in every such action shall be for the exclusive benefit of the surviving spouse and next of kin of such deceased person and in every such action the jury may give such damages as they shall deem a fair and just compensation with reference to the pecuniary injuries resulting from such death, to the surviving spouse and next of kin of such deceased person. (740 ILCS 180/2)."

23. That decedent left surviving her heirs entitled to recover under the Act, including her legal adoptive mother and five brothers.

WHEREFORE, the Plaintiff, ANGELA PARKER, Special Administrator of the Estate of SAMANTHA PARKER, Deceased, demands judgment against the Defendant, ZOLL, in a dollar amount in excess of the jurisdictional limitation of this Court, and for such other and further amounts as the jury and the Court shall deem proper, plus the cost of this suit.

COUNT 6 –SURVIVAL – NEGLIGENCE PER SE FOR VIOLATION THE ILLINOIS FOOD, DRUG, AND COSMETIC ACT - AGAINST ZOLL

NOW COMES the Plaintiff, ANGELA PARKER, Special Administrator, of the Estate of SAMANTHA PARKER, Deceased, by and through her attorneys, GOLDBERG & GOLDBERG, and complains of the Defendant, ZOLL, and Defendant SUSAN O'MARA as follows:

1. Plaintiff incorporates and re-pleads Count 5, paragraphs 1-19.

2. That at all relevant times, there was in full force and effect in the State of Illinois, a certain Act, commonly known as the Survival Death Act, 755 ILCS 5/27-6, which provided in pertinent part as follows:

3. "Actions which survive. In addition to the actions which survive by the common law, the following also survive: actions of replevin, actions to recover damages for an injury to the person (except slander and libel), actions to recover damages for an injury to real or personal property or for the detention or conversation of personal property, actions against officers for misfeasance, malfeasance, nonfeasance of themselves or their deputies, actions for fraud or deceit, and actions provided in Section 6-21 of 'An Act relating to alcoholic liquors'." (755 ILCS 5/27-6).

4. That decedent left surviving her heirs entitled to recover under the Act, including her adoptive mother and five brothers.

5. That prior to her death, SAMANTHA PARKER, suffered injuries of a personal and pecuniary nature that were direct and proximately caused by the acts and/or omissions of the defendant.

6. Additionally, as this claim is not based on strict product liability Plaintiff also seeks punitive damages for ZOLL's actions.

WHEREFORE, the Plaintiff, ANGELA PARKER, Special Administrator of the Estate of SAMANTHA PARKER, Deceased, demands judgment against the Defendant, ZOLL, in a dollar amount in excess of the jurisdictional limitation of this Court, and for such other and further amounts as the jury and the Court shall deem proper, plus the cost of this suit.

COUNT 7 - WRONGFUL DEATH - STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT - AGAINST ZOLL

NOW COMES the Plaintiff, ANGELA PARKER, Special Administrator, of the Estate of SAMANTHA PARKER, Deceased, by and through her attorneys, GOLDBERG & GOLDBERG, and complains of the Defendant, ZOLL, as follows:

1. Plaintiff incorporates introductory paragraphs 1-77 as set forth above.

2. On or about October 17, 2017, SAMANTHA PARKER was injured and died as a result of using the ZOLL LifeVest 4000.

3. At the time the subject ZOLL LifeVest left the control of defendant ZOLL there existed a condition which made the subject LifeVest unreasonably dangerous in one or more of the following respects:

a. There existed manufacturing defects in the diagnostic and detection software installed by ZOLL; and/or
b. There existed manufacturing defects in the treatment software installed by ZOLL; and/or
c. There existed manufacturing defects in the heart sensors, or electrodes, preventing accurate monitoring of heart rate; and/or
d. There existed manufacturing defects in the connector which connects the electrode belt to the monitor; and/or
e. There existed manufacturing defects in the vibration box which connects the heart sensors to the therapy pads; and/or
f. There existed manufacturing defects in the therapy pads used to administer therapeutic electric shocks; and/or
g. There existed manufacturing defects in the ZOLL Lifevest 4000 rendering it an unsafe product.

4. The cause of one or more of the above defects was ZOLL's violation of Federal Law as outlined by the FDA's Warning Letter. As a result, claims of Strict Product Liability are not pre-empted by Federal Law. Bausch v. Stryker Corp., 630 F.3d 546, 550 (7th Cir. 2010).

5. One or more of the above defects in the LifeVest provided to SAMANTHA PARKER resulted from a manufacturing defect.

6. The defective condition of the LifeVest made it unreasonably dangerous when it was provided to SAMANTHA PARKER.

7. One or more of the above defects existed in the subject LifeVest at the time it left ZOLL's control.

8. The subject LifeVest was not modified, altered, or changed from the time it left ZOLL's control.

9. That as a direct and proximate result of a manufacturing defect in the LifeVest, the plaintiff's decedent, SAMANTHA PARKER, died on October 17, 2015, or soon thereafter, when her ZOLL LifeVest 4000 failed to provide a necessary electric shock therapy during a defibrillation event.

10. That at all relevant times, there was in full force and effect in the State of Illinois, a certain Act, commonly known as the Wrongful Death Act, 740 ILCS 180/1-2 et seq., which provided in pertinent part as follows:

11. "Whenever the death of a person shall be caused by wrongful act, neglect or default, and the act, neglect or default is such as would, if death had ensued, have entitled the party injured to maintain an action and recover damages in respect thereof, then and in every such case the person who or company or corporation which would have been liable if death had not ensued, shall be liable

to an action for damages, notwithstanding the death of the person injured and although the death shall have been caused under such circumstances as amount in law to felon. (740 ILCS 180/1)

12. Every such action shall be brought by and in the names of the personal representatives of such deceased person, and, except as otherwise hereinafter provided, the amount recovered in every such action shall be for the exclusive benefit of the surviving spouse and next of kin of such deceased person and in every such action the jury may give such damages as they shall deem a fair and just compensation with reference to the pecuniary injuries resulting from such death, to the surviving spouse and next of kin of such deceased person. (740 ILCS 180/2)."

13. That decedent left surviving her heirs entitled to recover under the Act, including her legal adoptive mother and five brothers.

14. As a result of SAMANTHA PARKER'S death, Plaintiff continues to suffer damages, including but not limited to damages for (1) loss of support and services, (2) loss of companionship and protection, (3) mental suffering, (4) medical and (5) funeral expense.

WHEREFORE, the Plaintiff, ANGELA PARKER, Special Administrator of the Estate of SAMANTHA PARKER, Deceased, demands judgment against the Defendant, ZOLL, in a dollar amount in excess of the jurisdictional limitation of this Court, and for such other and further amounts as the jury and the Court shall deem proper, plus the cost of this suit.

COUNT 8 - SURVIVAL - STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT - AGAINST ZOLL

NOW COMES the Plaintiff, ANGELA PARKER, Special Administrator, of the Estate of SAMANTHA PARKER, Deceased, by and through her attorneys, GOLDBERG & GOLDBERG, and complains of the Defendant, ZOLL, as follows:

1. Plaintiff incorporates and re-pleads Count 7, paragraphs 1-9, as set forth above.

2. As a result of one or more of the above defects, prior to her death SAMANTHA PARKER suffered conscious pain and suffering.

3. That at all relevant times, there was in full force and effect in the State of Illinois, a certain Act, commonly known as the Survival Death Act, 755 ILCS 5/27-6, which provided in pertinent part as follows:

4. "Actions which survive. In addition to the actions which survive by the common law, the following also survive: actions of replevin, actions to recover

damages for an injury to the person (except slander and libel), actions to recover damages for an injury to real or personal property or for the detention or conversation of personal property, actions against officers for misfeasance, malfeasance, nonfeasance of themselves or their deputies, actions for fraud or deceit, and actions provided in Section 6-21 of 'An Act relating to alcoholic liquors'." (755 ILCS 5/27-6).

5. That decedent left surviving her heirs entitled to recover under the Act, including her adoptive mother and five brothers.

6. That prior to her death, SAMANTHA PARKER, suffered injuries of a personal and pecuniary nature that were direct and proximately caused by the acts and/or omissions of the defendant.

WHEREFORE, the Plaintiff, ANGELA PARKER, Special Administrator of the Estate of SAMANTHA PARKER, Deceased, demands judgment against the Defendant, ZOLL, in a dollar amount in excess of the jurisdictional limitation of this Court, and for such other and further amounts as the jury and the Court shall deem proper, plus the cost of this suit.

COUNT 9 - WRONGFUL DEATH - NEGLIGENCE – MANUFACTURING DEFECT - AGAINST ZOLL

NOW COMES the Plaintiff, ANGELA PARKER, Special Administrator, of the Estate of SAMANTHA PARKER, Deceased, by and through her attorneys, GOLDBERG & GOLDBERG, and complains of the Defendant, ZOLL, as follows:

1. Plaintiff incorporates introductory paragraphs 1-77 as set forth above.

2. On October 16, 2015, SUSAN O'MARA, provided the LifeVest to SAMANTHA PARKER at RENAISSANCE AT MIDWAY.

3. At that time SUSAN O'MARA was a ZOLL Patient Services Representative, was an employee of ZOLL, was compensated by ZOLL, and was acting as an agent of ZOLL.

4. SUSAN O'MARA had SAMANTHA PARKER sign a contract with ZOLL.

5. The contract obligated SAMANTHA PARKER to pay for the services provided by ZOLL and to use the LifeVest.

6. SUSAN O'MARA, ZOLL's agent, signed the same contract.

7. ZOLL owed SAMANTHA PARKER a duty, in part, because of the contractually relationship established on that day, to ensure the LifeVest was

manufactured in conformity with Good Manufacturing Practice requirements of the Quality System, and was manufactured in conformity with Federal Law.

8. ZOLL breached this duty as established by the FDA Warning Letter.

9. By breaching this duty ZOLL deviated from the standard of care that other manufacturers in the medical device industry follow.

10. Alternatively, by breaching this duty, ZOLL knew or should have known, in the exercise of due care, that the LifeVest was unreasonably dangerous.

11. As a result of ZOLL's breach of duty, when the subject ZOLL LifeVest left the control of defendant ZOLL there existed a condition which made the subject LifeVest unreasonably dangerous in one or more of the following respects:

a. There existed manufacturing defects in the diagnostic and detection software installed by ZOLL; and/or
b. There existed manufacturing defects in the treatment software installed by ZOLL; and/or
c. There existed manufacturing defects in the heart sensors, or electrodes, preventing accurate monitoring of heart rate; and/or
d. There existed manufacturing defects in the connector which connects the electrode belt to the monitor; and/or
e. There existed manufacturing defects in the vibration box which connects the heart sensors to the therapy pads; and/or
f. There existed manufacturing defects in the therapy pads used to administer therapeutic electric shocks; and/or
g. There existed manufacturing defects in the ZOLL Lifevest 4000 rendering it an unsafe product.

12. The cause of one or more of the above defects was ZOLL's violation of Federal Law as outlined by the FDA's Warning Letter. As a result, claims of Negligence are not pre-empted by Federal Law. Bausch v. Stryker Corp., 630 F.3d 546, 550 (7th Cir. 2010).

13. ZOLL did not provide SAMANTHA PARKER any warnings regarding the manufacturing defects.

14. ZOLL did not provide SAMANTHA PARKER any warning that the LifeVest was unreasonably dangerous.

15. That as a direct and proximate result of ZOLL's negligence, the plaintiff's decedent, SAMANTHA PARKER, died on October 17, 2015, or soon thereafter, when her ZOLL LifeVest failed to provide a necessary electric shock therapy during a defibrillation event.

16. One or more of the above defects was a proximate cause of SAMANTHA PARKER'S injuries and death.

17. One or more of the above defects, was a proximate cause of SAMANTHA PARKER's conscious pain and suffering, prior to her death.

18. That at all relevant times, there was in full force and effect in the State of Illinois, a certain Act, commonly known as the Wrongful Death Act, 740 ILCS 180/1-2 et seq., which provided in pertinent part as follows:

19. "Whenever the death of a person shall be caused by wrongful act, neglect or default, and the act, neglect or default is such as would, if death had ensued, have entitled the party injured to maintain an action and recover damages in respect thereof, then and in every such case the person who or company or corporation which would have been liable if death had not ensued, shall be liable to an action for damages, notwithstanding the death of the person injured and although the death shall have been caused under such circumstances as amount in law to felon. (740 ILCS 180/1)

20. Every such action shall be brought by and in the names of the personal representatives of such deceased person, and, except as otherwise hereinafter provided, the amount recovered in every such action shall be for the exclusive benefit of the surviving spouse and next of kin of such deceased person and in every such action the jury may give such damages as they shall deem a fair and just compensation with reference to the pecuniary injuries resulting from such death, to the surviving spouse and next of kin of such deceased person. (740 ILCS 180/2)."

21. That decedent left surviving her heirs entitled to recover under the Act, including her legal adoptive mother and five brothers.

22. As a result of SAMANTHA PARKER'S death, Plaintiff continues to suffer damages, including but not limited to damages for (1) loss of support and services, (2) loss of companionship and protection, (3) mental suffering, (4) medical and (5) funeral expense.

WHEREFORE, the Plaintiff, ANGELA PARKER, Special Administrator of the Estate of SAMANTHA PARKER, Deceased, demands judgment against the Defendant, ZOLL, in a dollar amount in excess of the jurisdictional limitation of this Court, and for such other and further amounts as the jury and the Court shall deem proper, plus the cost of this suit.

COUNT 10 - SURVIVAL - NEGLIGENCE – MANUFACTURING DEFECT - AGAINST ZOLL

NOW COMES the Plaintiff, ANGELA PARKER, Special Administrator, of the Estate of SAMANTHA PARKER, Deceased, by and through her attorneys, GOLDBERG & GOLDBERG, and complains of the Defendant, ZOLL, as follows:

1. Plaintiff incorporates and re-pleads Count 9, paragraphs 1-17.

2. That at all relevant times, there was in full force and effect in the State of Illinois, a certain Act, commonly known as the Survival Death Act, 755 ILCS 5/27-6, which provided in pertinent part as follows:

3. "Actions which survive. In addition to the actions which survive by the common law, the following also survive: actions of replevin, actions to recover damages for an injury to the person (except slander and libel), actions to recover damages for an injury to real or personal property or for the detention or conversation of personal property, actions against officers for misfeasance, malfeasance, nonfeasance of themselves or their deputies, actions for fraud or deceit, and actions provided in Section 6-21 of 'An Act relating to alcoholic liquors'." (755 ILCS 5/27-6).

4. That decedent left surviving her heirs entitled to recover under the Act, including her adoptive mother and five brothers.

5. That prior to her death, SAMANTHA PARKER, suffered injuries of a personal and pecuniary nature that were direct and proximately caused by the acts and/or omissions of the defendant.

WHEREFORE, the Plaintiff, ANGELA PARKER, Special Administrator of the Estate of SAMANTHA PARKER, Deceased, demands judgment against the Defendant, ZOLL, in a dollar amount in excess of the jurisdictional limitation of this Court, and for such other and further amounts as the jury and the Court shall deem proper, plus the cost of this suit.

COUNT 11 – WRONGFUL DEATH - STRICT PRODUCT LIABILITY - FAILURE TO WARN - AGAINST ZOLL

NOW COMES the Plaintiff, ANGELA PARKER, Special Administrator, of the Estate of SAMANTHA PARKER, Deceased, by and through her attorneys, GOLDBERG & GOLDBERG, and complains of the Defendant, ZOLL, as follows:

1. Plaintiff incorporates introductory paragraphs 1-77 as set forth above.

2. On or about October 17, 2017, SAMANTHA PARKER was injured and died as a result of using the ZOLL LifeVest 4000.

3. At the time the ZOLL LifeVest 4000 left the control of defendant ZOLL there existed a condition which made the LifeVest 4000 unreasonably dangerous in one or more of the following respects:

a. There existed manufacturing defects in the diagnostic and detection software installed by ZOLL; and/or
b. There existed manufacturing defects in the treatment software installed by ZOLL; and/or
c. There existed manufacturing defects in the heart sensors, or electrodes, preventing accurate monitoring of heart rate; and/or
d. There existed manufacturing defects in the connector which connects the electrode belt to the monitor; and/or
e. There existed manufacturing defects in the vibration box which connects the heart sensors to the therapy pads; and/or
f. There existed manufacturing defects in the therapy pads used to administer therapeutic electric shocks; and/or
g. There existed manufacturing defects in the ZOLL LifeVest rendering it an unsafe product.

4. The cause of one or more of the above defects was ZOLL's violation of Federal Law as outlined by the FDA's Warning Letter. As a result, claims of Strict Product Liability are not pre-empted by Federal Law. Bausch v. Stryker Corp., 630 F.3d 546, 550 (7th Cir. 2010).

5. ZOLL had unequal knowledge of the above defects in the LifeVest caused by ZOLL's violation of Federal Law as described in the Warning Letter.

6. ZOLL had unequal knowledge the increased risk of harm of the LifeVest.

7. ZOLL had a duty to warn SAMANTHA PARKER that:

a. The LifeVest was an adulterated medical device by Federal Law; and/or
b. The LifeVest was an adulterated medical device by Illinois Law; and/or
c. The LifeVest was a misbranded medical device by Federal Law; and/or
d. The LifeVest was a misbranded medical device by Illinois Law; and/or
e. Approximately half of all treatments administered to patients were inappropriate shocks; and/or
f. ZOLL failed to document corrective and preventative actions; and/or
g. ZOLL failed to thoroughly investigate, review, and evaluate complaints through ZOLL's Regulatory Affairs Office; and/or

h. ZOLL failed to adequately establish procedures for design validation and not adequate validating the LifeVest under actual or simulated use conditions; and/or
i. ZOLL was negligent because the management with executive responsibility failed to review the suitability and effectiveness of the quality system at defined intervals, and with sufficient frequency, according to established procedures; and/or
j. An F.D.A. inspection determined the LifeVest was misbranded.
k. ZOLL failed to provide adequate warnings or information about the "true safety risks" associated with LifeVest use;
l. ZOLL failed to provide adequate warnings or information about the protocol for intervening or stabilizing patients who suffer from V-fib or V-tach, but never receive a therapeutic shock from the LifeVest;
m. ZOLL failed to investigate, research, study and define, the safety profile of the LifeVest;
n. ZOLL failed to include a "Boxed Warning" or a "Bolded Warning" about serious failures to provide a therapeutic shock associated with LifeVest use.

8. That as a direct and proximate result of ZOLL's failure to warn SAMANTHA PARKER of the unreasonable risk of harm she died on October 17, 2015, or soon thereafter, when her ZOLL LifeVest 4000 failed to provide a necessary electric shock therapy during a defibrillation event.

9. At all relevant times, there was in full force and effect in the State of Illinois, a certain Act, commonly known as the Wrongful Death Act, 740 ILCS 180/1-2 et seq., which provided in pertinent part as follows:

10. "Whenever the death of a person shall be caused by wrongful act, neglect or default, and the act, neglect or default is such as would, if death had ensued, have entitled the party injured to maintain an action and recover damages in respect thereof, then and in every such case the person who or company or corporation which would have been liable if death had not ensued, shall be liable to an action for damages, notwithstanding the death of the person injured and although the death shall have been caused under such circumstances as amount in law to felon. (740 ILCS 180/1)

11. Every such action shall be brought by and in the names of the personal representatives of such deceased person, and, except as otherwise hereinafter provided, the amount recovered in every such action shall be for the exclusive benefit of the surviving spouse and next of kin of such deceased person and in every such action the jury may give such damages as they shall deem a fair and just compensation with reference to the pecuniary injuries resulting from such death, to the surviving spouse and next of kin of such deceased person. (740 ILCS 180/2)."

12. That decedent left surviving her heirs entitled to recover under the Act, including her legal adoptive mother and five brothers.

13. As a result of SAMANTHA PARKER'S death, Plaintiff continues to suffer damages, including but not limited to damages for (1) loss of support and services, (2) loss of companionship and protection, (3) mental suffering, (4) medical and (5) funeral expense.

WHEREFORE, the Plaintiff, ANGELA PARKER, Special Administrator of the Estate of SAMANTHA PARKER, Deceased, demands judgment against the Defendant, ZOLL, in a dollar amount in excess of the jurisdictional limitation of this Court, and for such other and further amounts as the jury and the Court shall deem proper, plus the cost of this suit.

COUNT 12 – SURVIVAL - STRICT PRODUCT LIABILITY - FAILURE TO WARN - AGAINST ZOLL

NOW COMES the Plaintiff, ANGELA PARKER, Special Administrator, of the Estate of SAMANTHA PARKER, Deceased, by and through her attorneys, GOLDBERG & GOLDBERG, and complains of the Defendant, ZOLL, as follows:

1. Plaintiff incorporates and re-pleads Count 11, paragraphs 1-8 as set forth above.

2. As a result of one or more of the above defects, prior to her death SAMANTHA PARKER suffered conscious pain and suffering.

3. That at all relevant times, there was in full force and effect in the State of Illinois, a certain Act, commonly known as the Survival Death Act, 755 ILCS 5/27-6, which provided in pertinent part as follows:

4. "Actions which survive. In addition to the actions which survive by the common law, the following also survive: actions of replevin, actions to recover damages for an injury to the person (except slander and libel), actions to recover damages for an injury to real or personal property or for the detention or conversation of personal property, actions against officers for misfeasance, malfeasance, nonfeasance of themselves or their deputies, actions for fraud or deceit, and actions provided in Section 6-21 of 'An Act relating to alcoholic liquors'." (755 ILCS 5/27-6).

5. That decedent left surviving her heirs entitled to recover under the Act, including her adoptive mother and five brothers.

6. That prior to her death, SAMANTHA PARKER, suffered injuries of a personal and pecuniary nature that were direct and proximately caused by the acts and/or omissions of the defendant.

WHEREFORE, the Plaintiff, ANGELA PARKER, Special Administrator of the Estate of SAMANTHA PARKER, Deceased, demands judgment against the Defendant, ZOLL, in a dollar amount in excess of the jurisdictional limitation of this Court, and for such other and further amounts as the jury and the Court shall deem proper, plus the cost of this suit.

COUNT 13 – VIOLATION OF THE ILLINOIS CONSUMER FRAUD AND DECEPTIVE BUSINESS PRACTICES ACT - AGAINST ZOLL

NOW COMES the Plaintiff, ANGELA PARKER, Special Administrator, of the Estate of SAMANTHA PARKER, Deceased, by and through her attorneys, GOLDBERG & GOLDBERG, and complains of the Defendant, ZOLL, as follows:

1. Plaintiff incorporates introductory paragraphs 1-77 as set forth above.

2. On or about October 17, 2017, SAMANTHA PARKER was injured and died as a result of using the ZOLL LifeVest 4000.

3. At that time the Consumer Fraud and Deceptive Business Practices Act was in full force and effect. (815 ILCS 505).

4. In connection with promoting and convincing physicians to prescribe and patients to use its LifeVest devices, ZOLL makes Marketing Statements on its website and directly to physicians and patients.

5. The Marketing Statements state that:

   a. patients may "return to their activities of daily living, while having the peace of mind that they are protected from SCA."
   b. the LifeVest provides "constant monitoring, immediate protection, and offers peace of mind for patients."
   c. "[i]f a life-threatening heart rhythm is detected, the device delivers a treatment shock to restore normal heart rhythm."
   d. The entire event, "from detecting a life-threatening arrhythmia to automatically delivering a treatment shock, usually occurs in less than a minute."
   e. The LifeVest "has a **98 percent first treatment shock success rate** for resuscitating patients from SCA."

6. ZOLL failed, among other things, to establish and maintain procedures for:

   a. Analyzing processes, work operations, quality records, and other information to identify existing and potential causes of nonconforming product;

b. Investigating the cause of nonconformities;
c. Identifying appropriate actions needed to correct and prevent recurrence of nonconforming product;
d. Verifying and validating that the appropriate actions to prevent and remedy nonconformities were effective;
e. Documenting the processes and actions above.

7. As a result of ZOLL's failures, ZOLL could not know and did not know the success rate of the LifeVest, including whether the LifeVest did in fact have a 98 percent first treatment shock success rate.

8. ZOLL knew or should have known that the Marketing Statements were false and/or unsubstantiated when they were made.

9. ZOLL never warned SAMANTHA PARKER that:

a. The LifeVest was an adulterated medical device by Federal Law; and/or
b. The LifeVest was an adulterated medical device by Illinois Law; and/or
c. The LifeVest was a misbranded medical device by Federal Law; and/or
d. The LifeVest was a misbranded medical device by Illinois Law; and/or
e. Approximately half of all treatments administered to patients were inappropriate shocks; and/or
f. ZOLL failed to document corrective and preventative actions; and/or
g. ZOLL failed to thoroughly investigate, review, and evaluate complaints through ZOLL's Regulatory Affairs Office; and/or
h. ZOLL failed to adequately establish procedures for design validation and not adequate validating the LifeVest under actual or simulated use conditions; and/or
i. ZOLL was negligent because the management with executive responsibility failed to review the suitability and effectiveness of the quality system at defined intervals, and with sufficient frequency, according to established procedures; and/or
j. An F.D.A. inspection determined the LifeVest was misbranded; and/or
k. ZOLL failed to provide adequate warnings or information about the "true safety risks" associated with LifeVest use; and/or
l. ZOLL failed to provide adequate warnings or information about the protocol for intervening or stabilizing patients who suffer from V-fib or V-tach, but never receive a therapeutic shock from the LifeVest; and/or
m. ZOLL failed to investigate, research, study and define, fully and adequately, the safety profile of the LifeVest; and/or
n. ZOLL failed to include a "Boxed Warning" or a "Bolded Warning" about serious failures to provide a therapeutic shock associated with LifeVest use.

10. ZOLL's failure to inform Samantha Parker of one or more of the above facts constituted a deceptive act or practice in that it constitutes:

a. Suppression and/or omission or a material fact; and/or
b. Misrepresentation or concealment of a fact.

11. ZOLL intended for SAMANTHA PARKER and her physicians to rely on its above omissions, suppressions, misrepresentations, and/or concealment.

12. The deception occurred in the course conduct involving trade or commerce, namely ZOLL obtaining contractual obligation from SAMANTHA PARKER to pay for ZOLL's LifeVest and related services.

13. The cause of one or more of the suppressed, omitted, misrepresented, or concealed facts was ZOLL's violation of Federal Law as outlined by the FDA's Warning Letter. As a result, claims of Consumer Fraud and Deceptive Business Practices Act are not pre-empted by Federal Law. See Bausch v. Stryker Corp., 630 F.3d 546, 550 (7th Cir. 2010).

14. That as a direct and proximate result of ZOLL's violation of the Consumer Fraud and Deceptive Business Practices Act, SAMANTHA PARKER, suffered injury and death when her ZOLL LifeVest 4000 failed to provide a necessary electric shock therapy during a defibrillation event.

WHEREFORE, the Plaintiff, ANGELA PARKER, Special Administrator of the Estate of SAMANTHA PARKER, Deceased, demands judgment against the Defendant, ZOLL, in a dollar amount in excess of the jurisdictional limitation of this Court for actual economic damages, punitive damages, reasonable attorney fees, court costs, and any other relief which this Court deems proper.

COUNT 14 – WRONGFUL DEATH - NEGLIGENCE - FAILURE TO WARN LEARNED INTERMEDIARY - AGAINST ZOLL

NOW COMES the Plaintiff, ANGELA PARKER, Special Administrator, of the Estate of SAMANTHA PARKER, Deceased, by and through her attorneys, GOLDBERG & GOLDBERG, and complains of the Defendant, ZOLL, as follows:

1. Plaintiffs' incorporate introductory paragraphs 1-77 as set forth above.

2. The LifeVest 4000 involved in this case can only be obtained with a prescription from a physician.

3. For this reason, defendant ZOLL had a duty to adequately warn AMER HUSSEINI, M.D., and/or MALKAN PATEL, M.D. of the dangers of which it knew, or in the exercise of ordinary care should have known, at the time the LifeVest 4000 left defendant ZOLL's control.

4. Notwithstanding this duty, defendant ZOLL violated this duty when it failed to warn AMER HUSSEINI, M.D., and/or MALKAN PATEL, M.D. that:

a. The LifeVest was an adulterated medical device by Federal Law; and/or
b. The LifeVest was an adulterated medical device by Illinois Law; and/or
c. The LifeVest was a misbranded medical device by Federal Law; and/or
d. The LifeVest was a misbranded medical device by Illinois Law; and/or
e. Approximately half of all treatments administered to patients were inappropriate shocks; and/or
f. ZOLL failed to document corrective and preventative actions; and/or
g. ZOLL failed to thoroughly investigate, review, and evaluate complaints through ZOLL's Regulatory Affairs Office; and/or
h. ZOLL failed to adequately establish procedures for design validation and not adequate validating the LifeVest under actual or simulated use conditions; and/or
i. ZOLL was negligent because the management with executive responsibility failed to review the suitability and effectiveness of the quality system at defined intervals, and with sufficient frequency, according to established procedures; and/or
j. an F.D.A. inspection determined the LifeVest was misbranded.
k. ZOLL failed to provide adequate warnings or information about the "true safety risks" associated with LifeVest use;
l. ZOLL failed to provide adequate warnings or information about the protocol for intervening or stabilizing patients who suffer from V-fib or V-tach, but never receive a therapeutic shock from the LifeVest;
m. ZOLL failed to investigate, research, study and define, fully and adequately, the safety profile of the LifeVest;
n. Zoll failed to include a "Boxed Warning" or a "Bolded Warning" about serious failures to provide a therapeutic shock associated with LifeVest use.

5. The reason for providing the warnings was ZOLL's violation of Federal Law as outlined by the FDA's Warning Letter. As a result, claims of Negligence are not pre-empted by Federal Law. Bausch v. Stryker Corp., 630 F.3d 546, 550 (7th Cir. 2010).

6. As a result of one or more of these failures, AMER HUSSEINI, M.D., and/or MALKAN PATEL, M.D., were unaware that the LifeVest 4000 was an unreasonably dangerous product and prescribed the LifeVest 4000 to SAMANTHA PARKER.

7. On October 17, 2015, as a result of SAMANTHA PARKER'S use of the LifeVest 4000, she was injured causing her death.

8. Defendant ZOLL's failures to warn DR. AMER HUSSEINI, M.D., and/or DR. MALKAN PATEL, M.D. of the dangers known to ZOLL were a proximate cause of SAMANTHA PARKER'S death.

9. Defendant ZOLL's failures to warn DR. AMER HUSSEINI, M.D., and/or DR. MALKAN PATEL, M.D. of the dangers known to ZOLL were a proximate cause of SAMANTHA PARKER suffered conscious pain and suffering prior to her death.

10. At all relevant times, there was in full force and effect in the State of Illinois, a certain Act, commonly known as the Wrongful Death Act, 740 ILCS 180/1-2 et seq., which provided in pertinent part as follows:

11. "Whenever the death of a person shall be caused by wrongful act, neglect or default, and the act, neglect or default is such as would, if death had ensued, have entitled the party injured to maintain an action and recover damages in respect thereof, then and in every such case the person who or company or corporation which would have been liable if death had not ensued, shall be liable to an action for damages, notwithstanding the death of the person injured and although the death shall have been caused under such circumstances as amount in law to felon. (740 ILCS 180/1)

12. Every such action shall be brought by and in the names of the personal representatives of such deceased person, and, except as otherwise hereinafter provided, the amount recovered in every such action shall be for the exclusive benefit of the surviving spouse and next of kin of such deceased person and in every such action the jury may give such damages as they shall deem a fair and just compensation with reference to the pecuniary injuries resulting from such death, to the surviving spouse and next of kin of such deceased person. (740 ILCS 180/2)."

13. That decedent left surviving her heirs entitled to recover under the Act, including her legal adoptive mother and five brothers.

14. As a result of SAMANTHA PARKER'S death, Plaintiff continues to suffer damages, including but not limited to damages for (1) loss of support and services, (2) loss of companionship and protection, (3) mental suffering, (4) medical and (5) funeral expense.

WHEREFORE, the Plaintiff, ANGELA PARKER, Special Administrator of the Estate of SAMANTHA PARKER, Deceased, demands judgment against the Defendant, ZOLL, in a dollar amount in excess of the jurisdictional limitation of this Court, and for such other and further amounts as the jury and the Court shall deem proper, plus the cost of this suit.

COUNT 15 – SURVIVAL - NEGLIGENCE - FAILURE TO WARN LEARNED INTERMEDIARY - AGAINST ZOLL

1. Plaintiff incorporates and re-pleads Count 14, paragraph 1-9.

2. That at all relevant times, there was in full force and effect in the State of Illinois, a certain Act, commonly known as the Survival Death Act, 755 ILCS 5/27-6, which provided in pertinent part as follows:

3. "Actions which survive. In addition to the actions which survive by the common law, the following also survive: actions of replevin, actions to recover damages for an injury to the person (except slander and libel), actions to recover damages for an injury to real or personal property or for the detention or conversation of personal property, actions against officers for misfeasance, malfeasance, nonfeasance of themselves or their deputies, actions for fraud or deceit, and actions provided in Section 6-21 of 'An Act relating to alcoholic liquors'." (755 ILCS 5/27-6).

4. That decedent left surviving her heirs entitled to recover under the Act, including her adoptive mother and five brothers.

5. That prior to her death, SAMANTHA PARKER, suffered injuries of a personal and pecuniary nature that were direct and proximately caused by the acts and/or omissions of the defendant.

WHEREFORE, the Plaintiff, ANGELA PARKER, Special Administrator of the Estate of SAMANTHA PARKER, Deceased, demands judgment against the Defendant, ZOLL, in a dollar amount in excess of the jurisdictional limitation of this Court, and for such other and further amounts as the jury and the Court shall deem proper, plus the cost of this suit.

COUNT 16– WRONGFUL DEATH - STRICT PRODUCT LIABILITY – DISTRIBUTOR – AGAINST RENAISSANCE AT MIDWAY, INC.

NOW COMES the Plaintiff, ANGELA PARKER, Special Administrator, of the Estate of SAMANTHA PARKER, Deceased, by and through her attorneys, GOLDBERG & GOLDBERG, and complains of the Defendant, RENAISSANCE AT MIDWAY, INC., as follows:

1. Plaintiffs' incorporate introductory paragraphs 1-77 as set forth above.

2. On or about October 17, 2017, SAMANTHA PARKER was injured and died as a result of using the ZOLL LifeVest 4000.

3. At the time the ZOLL LifeVest 4000 left the control of defendant ZOLL there existed a condition which made the LifeVest 4000 unreasonably dangerous in one or more of the following respects:

a. There existed defects in the diagnostic and detection software installed by ZOLL; and/or
b. There existed defects in the treatment software installed by ZOLL; and/or
c. There existed defects in the heart sensors, or electrodes, preventing accurate monitoring of heart rate; and/or
d. There existed defects in the connector which connects the electrode belt to the monitor; and/or
e. There existed defects in the vibration box which connects the heart sonsors to the therapy pads; and/or
f. There existed defects in the therapy pads used to administer therapeutic electric shocks; and/or
g. By Illinois Law the ZOLL LifeVest 4000 was considered an adulterated medical device; and/or
h. Appoximately half of all treatments administered to patients were inappropriate shocks; and/or
i. ZOLL failed to document corrective and preventative actions; and/or
j. ZOLL failed to thoroughly investigate, review, and evaluate complaints through ZOLL's Regulatory Affairs Office; and/or
k. ZOLL failed to adequately establish procedures for design validation and not adequate validating the LifeVest 4000 under actual or simulated use conditions; and/or
l. ZOLL was negligent because the management with executive responsibility failed to review the suitability and effectiveness of the quality system at defined intervals, and with sufficient frequency, according to established procedures; and/or
m. An FDA inspection determined the LifeVest was misbranded.

4. One or more of the above defects made the subject LifeVest 4000 an unreasonably dangerous product to use.

5. The subject LifeVest 4000 reached SAMANTHA PARKER in the same manner it was placed into commerce by ZOLL and was not modified or changed before, during and after the time it was placed by ZOLL directly on and worn by SAMANTHA PARKER.

6. One or more of the above defects existed at the time the LifeVest 4000 left the control of defendant, ZOLL.

7. One or more of the above defects was a proximate cause of SAMANTHA PARKER'S injury and death.

8. Under Illinois law, defendants, RENAISSANCE AT MIDWAY, INC. was a member of the chain of distribution of the ZOLL LifeVest 4000.

9. RENAISSANCE AT MIDWAY, INC. had actual knowledge of one or more of the defects listed above.

10. At all relevant times, there was in full force and effect in the State of Illinois, a certain Act, commonly known as the Wrongful Death Act, 740 ILCS 180/1-2 et seq., which provided in pertinent part as follows:

11. "Whenever the death of a person shall be caused by wrongful act, neglect or default, and the act, neglect or default is such as would, if death had ensued, have entitled the party injured to maintain an action and recover damages in respect thereof, then and in every such case the person who or company or corporation which would have been liable if death had not ensued, shall be liable to an action for damages, notwithstanding the death of the person injured and although the death shall have been caused under such circumstances as amount in law to felon. (740 ILCS 180/1)

12. Every such action shall be brought by and in the names of the personal representatives of such deceased person, and, except as otherwise hereinafter provided, the amount recovered in every such action shall be for the exclusive benefit of the surviving spouse and next of kin of such deceased person and in every such action the jury may give such damages as they shall deem a fair and just compensation with reference to the pecuniary injuries resulting from such death, to the surviving spouse and next of kin of such deceased person. (740 ILCS 180/2)."

13. That decedent left surviving his heirs entitled to recover under the Act, including her legal adoptive mother and five brothers.

14. As a result of SAMANTHA PARKER'S death, Plaintiff continues to suffer damages, including but not limited to damages for (1) loss of support and services, (2) loss of companionship and protection, (3) mental suffering, (4) medical and (5) funeral expense.

WHEREFORE, the Plaintiff, ANGELA PARKER, Special Administrator of the Estate of SAMANTHA PARKER, Deceased, demands judgment against the Defendant, ZOLL, in a dollar amount in excess of the jurisdictional limitation of this Court, and for such other and further amounts as the jury and the Court shall deem proper, plus the cost of this suit.

COUNT 17 – WRONGFUL DEATH - FRAUDULENT MISREPRESENTATION - AGAINST ZOLL

NOW COMES the Plaintiff, ANGELA PARKER, Special Administrator, of the Estate of SAMANTHA PARKER, Deceased, by and through her attorneys, GOLDBERG & GOLDBERG, and complains of the Defendant, ZOLL, as follows:

1. Plaintiffs' incorporate introductory paragraphs 1-77 as though fully set forth herein.

2. ZOLL made the above mentioned Marketing Statements (introductory paragraphs 17-24).

3. ZOLL's agent, SUSAN O'MARA, provided these one or more of these Marketing Statements orally and through documents given to SAMANTHA PARKER on October 16, 2015.

4. The above Marketing Statements were false statements.

5. The Marketing Statements contained statements of material fact.

6. ZOLL knew the Marketing Statements were false because of the violations of Federal Law as outlined in the Warning Letter.

7. The reason for these Marketing Statements being false were ZOLL's violation of Federal Law as outlined by the FDA's Warning Letter. As a result, claims of Fraudulent Misrepresentation are not pre-empted by Federal Law. See Bausch v. Stryker Corp., 630 F.3d 546, 550 (7th Cir. 2010).

8. ZOLL made these statements with the intention to induce SAMANTHA PARKER to sign a contract and pay, individually and through her insurance, for the LifeVest and related ZOLL services.

9. SAMANTHA PARKER reasonably relied on the truth of ZOLL's Marketing Statements in her decision to wear the LifeVest instead of seeking alternative options to the LifeVest.

10. At all relevant times, there was in full force and effect in the State of Illinois, a certain Act, commonly known as the Wrongful Death Act, 740 ILCS 180/1-2 et seq., which provided in pertinent part as follows:

11. "Whenever the death of a person shall be caused by wrongful act, neglect or default, and the act, neglect or default is such as would, if death had ensued, have entitled the party injured to maintain an action and recover damages in respect thereof, then and in every such case the person who or company or corporation which would have been liable if death had not ensued, shall be liable

to an action for damages, notwithstanding the death of the person injured and although the death shall have been caused under such circumstances as amount in law to felon. (740 ILCS 180/1)

12. Every such action shall be brought by and in the names of the personal representatives of such deceased person, and, except as otherwise hereinafter provided, the amount recovered in every such action shall be for the exclusive benefit of the surviving spouse and next of kin of such deceased person and in every such action the jury may give such damages as they shall deem a fair and just compensation with reference to the pecuniary injuries resulting from such death, to the surviving spouse and next of kin of such deceased person. (740 ILCS 180/2)."

13. That decedent left surviving her heirs entitled to recover under the Act, including her legal adoptive mother and five brothers.

14. As a result of SAMANTHA PARKER'S death, Plaintiff continues to suffer damages, including but not limited to damages for (1) loss of support and services, (2) loss of companionship and protection, (3) mental suffering, (4) medical and (5) funeral expense.

WHEREFORE, the Plaintiff, ANGELA PARKER, Special Administrator of the Estate of SAMANTHA PARKER, Deceased, demands judgment against the Defendant, ZOLL, in a dollar amount in excess of the jurisdictional limitation of this Court, and for such other and further amounts as the jury and the Court shall deem proper, plus the cost of this suit.

COUNT 18 – SURVIVAL - FRAUDULENT MISREPRESENTATION - AGAINST ZOLL

NOW COMES the Plaintiff, ANGELA PARKER, Special Administrator, of the Estate of SAMANTHA PARKER, Deceased, by and through her attorneys, GOLDBERG & GOLDBERG, and complains of the Defendant, ZOLL, as follows:

1. Plaintiffs' incorporates and re-pleads Count 17, paragraphs 1-9.

2. That at all relevant times, there was in full force and effect in the State of Illinois, a certain Act, commonly known as the Survival Death Act, 755 ILCS 5/27-6, which provided in pertinent part as follows:

3. "Actions which survive. In addition to the actions which survive by the common law, the following also survive: actions of replevin, actions to recover damages for an injury to the person (except slander and libel), actions to recover damages for an injury to real or personal property or for the detention or conversation of personal property, actions against officers for misfeasance,

malfeasance, nonfeasance of themselves or their deputies, actions for fraud or deceit, and actions provided in Section 6-21 of 'An Act relating to alcoholic liquors'." (755 ILCS 5/27-6).

4. That decedent left surviving her heirs entitled to recover under the Act, including her adoptive mother and five brothers.

5. That prior to her death, SAMANTHA PARKER, suffered injuries of a personal and pecuniary nature that were direct and proximately caused by the acts and/or omissions of the defendant.

WHEREFORE, the Plaintiff, ANGELA PARKER, Special Administrator of the Estate of SAMANTHA PARKER, Deceased, demands judgment against the Defendant, ZOLL, in a dollar amount in excess of the jurisdictional limitation of this Court, and for such other and further amounts as the jury and the Court shall deem proper, plus the cost of this suit.

COUNT 19–WRONGFUL DEATH - NEGLIGENT MISREPRESENTATION AND OMISSION - AGAINST ZOLL

NOW COMES the Plaintiff, ANGELA PARKER, Special Administrator, of the Estate of SAMANTHA PARKER, Deceased, by and through her attorneys, GOLDBERG & GOLDBERG, and complains of the Defendant, ZOLL, as follows:

1. Plaintiff incorporates introductory paragraphs 1-77 as set forth above.

2. On October 16, 2015, SUSAN O'MARA, provided the LifeVest to SAMANTHA PARKER at RENAISSANCE AT MIDWAY.

3. At that time SUSAN O'MARA was a ZOLL Patient Services Representative, was an employee of ZOLL, was compensated by ZOLL, and was acting as an agent of ZOLL.

4. SUSAN O'MARA had SAMANTHA PARKER sign a contract with ZOLL.

5. The contract obligated SAMANTHA PARKER to pay for the services provided by ZOLL and to use the LifeVest.

6. SUSAN O'MARA signed the same contract.

7. SUSAN O'MARA fit SAMANTHA PARKER for the LifeVest.

8. SUSAN O'MARA trained SAMANTHA PARKER in the use of the LifeVest.

9. The above training included, but was not limited to how to operate the response buttons, how to charge the batteries, how to change the garment, and how to connect the LifeVest device to the telephone for transmission of data.

10. ZOLL owed SAMANTHA PARKER a duty to communicate accurate information because of the contractually relationship established on that day.

11. SUSAN O'MARA, as an agent of ZOLL, and as part of her business of supplying information for the guidance regarding the ZOLL LifeVest also owed a duty to SAMANTHA PARKER to communicate accurate information.

12. ZOLL made the above mentioned Marketing Statements. (Introductory paragraphs 17-24).

13. ZOLL's agent, SUSAN O'MARA, provided one or more of the Marketing Statements orally and through documents given to SAMANTHA PARKER on October 16, 2015.

14. The above Marketing Statements were false statements.

15. The Marketing Statements contained statements of material fact.

16. ZOLL knew the Marketing Statements were false because of the violations of Federal Law as outlined in the Warning Letter.

17. Additionally, ZOLL and SUSAN O'MARA, ZOLL's agent, negligently omitted the following information when SAMANTHA PARKER was fitted, educated, and trained to use the LifeVest:

a. The LifeVest was an adulterated medical device by Federal Law; and/or
b. The LifeVest was an adulterated medical device by Illinois Law; and/or
c. The LifeVest was a misbranded medical device by Federal Law; and/or
d. The LifeVest was a misbranded medical device by Illinois Law; and/or
e. Approximately half of all treatments administered to patients were inappropriate shocks; and/or
f. ZOLL failed to document corrective and preventative actions; and/or
g. ZOLL failed to thoroughly investigate, review, and evaluate complaints through ZOLL's Regulatory Affairs Office; and/or
h. ZOLL failed to adequately establish procedures for design validation and not adequate validating the LifeVest under actual or simulated use conditions; and/or
i. ZOLL was negligent because the management with executive responsibility failed to review the suitability and effectiveness of the quality system at defined intervals, and with sufficient frequency, according to established procedures; and/or
j. An F.D.A. inspection determined the LifeVest was misbranded.

k. There existed defects in the diagnostic and detection software installed by ZOLL; and/or
l. There existed defects in the treatment software installed by ZOLL; and/or
m. There existed defects in the heart sensors, or electrodes, preventing accurate monitoring of heart rate; and/or
n. There existed defects in the connector which connects the electrode belt to the monitor; and/or
o. There existed defects in the vibration box which connects the heart sensors to the therapy pads; and/or
p. There existed defects in the therapy pads used to administer therapeutic electric shocks; and/or

18. The reason for these Marketing Statements being false and the duty to provide omitted information were ZOLL's violation of Federal Law as outlined by the FDA's Warning Letter. As a result, claims of Negligent Misrepresentation and omission are not pre-empted by Federal Law. See Bausch v. Stryker Corp., 630 F.3d 546, 550 (7th Cir. 2010).

19. ZOLL made these statements and omitted information with the intention to induce SAMANTHA PARKER to sign a contract and pay, individually and through her insurance, for the LifeVest and related ZOLL services.

20. SAMANTHA PARKER reasonably relied on the truth of ZOLL's Marketing Statements in her decision to wear the LifeVest instead of seeking alternative options to the LifeVest.

21. At all relevant times, there was in full force and effect in the State of Illinois, a certain Act, commonly known as the Wrongful Death Act, 740 ILCS 180/1-2 et seq., which provided in pertinent part as follows:

22. "Whenever the death of a person shall be caused by wrongful act, neglect or default, and the act, neglect or default is such as would, if death had ensued, have entitled the party injured to maintain an action and recover damages in respect thereof, then and in every such case the person who or company or corporation which would have been liable if death had not ensued, shall be liable to an action for damages, notwithstanding the death of the person injured and although the death shall have been caused under such circumstances as amount in law to felon. (740 ILCS 180/1)

23. Every such action shall be brought by and in the names of the personal representatives of such deceased person, and, except as otherwise hereinafter provided, the amount recovered in every such action shall be for the exclusive benefit of the surviving spouse and next of kin of such deceased person and in every such action the jury may give such damages as they shall deem a fair and

just compensation with reference to the pecuniary injuries resulting from such death, to the surviving spouse and next of kin of such deceased person. (740 ILCS 180/2)."

24. That decedent left surviving her heirs entitled to recover under the Act, including her legal adoptive mother and five brothers.

25. As a result of SAMANTHA PARKER'S death, Plaintiff continues to suffer damages, including but not limited to damages for (1) loss of support and services, (2) loss of companionship and protection, (3) mental suffering, (4) medical and (5) funeral expense.

WHEREFORE, the Plaintiff, ANGELA PARKER, Special Administrator of the Estate of SAMANTHA PARKER, Deceased, demands judgment against the Defendant, ZOLL, in a dollar amount in excess of the jurisdictional limitation of this Court, and for such other and further amounts as the jury and the Court shall deem proper, plus the cost of this suit

COUNT 20 –SURVIVAL - NEGLIGENT MISREPRESENTATION AND OMISSION - AGAINST ZOLL

NOW COMES the Plaintiff, ANGELA PARKER, Special Administrator, of the Estate of SAMANTHA PARKER, Deceased, by and through her attorneys, GOLDBERG & GOLDBERG, and complains of the Defendant, ZOLL, as follows:

1. Plaintiff incorporates and re-pleads, Count 19, paragraphs 1-20 as set forth above.

2. That at all relevant times, there was in full force and effect in the State of Illinois, a certain Act, commonly known as the Survival Death Act, 755 ILCS 5/27-6, which provided in pertinent part as follows:

3. "Actions which survive. In addition to the actions which survive by the common law, the following also survive: actions of replevin, actions to recover damages for an injury to the person (except slander and libel), actions to recover damages for an injury to real or personal property or for the detention or conversation of personal property, actions against officers for misfeasance, malfeasance, nonfeasance of themselves or their deputies, actions for fraud or deceit, and actions provided in Section 6-21 of 'An Act relating to alcoholic liquors'." (755 ILCS 5/27-6).

4. That decedent left surviving her heirs entitled to recover under the Act, including her adoptive mother and five brothers.

5. That prior to her death, SAMANTHA PARKER, suffered injuries of a personal and pecuniary nature that were direct and proximately caused by the acts and/or omissions of the defendant.

WHEREFORE, the Plaintiff, ANGELA PARKER, Special Administrator of the Estate of SAMANTHA PARKER, Deceased, demands judgment against the Defendant, ZOLL, in a dollar amount in excess of the jurisdictional limitation of this Court, and for such other and further amounts as the jury and the Court shall deem proper, plus the cost of this suit.

COUNT 21 - BREACH OF EXPRESS WARRANTY - AGAINST ZOLL

NOW COMES the Plaintiff, ANGELA PARKER, Special Administrator, of the Estate of SAMANTHA PARKER, Deceased, by and through her attorneys, GOLDBERG & GOLDBERG, and complains of the Defendant, ZOLL as follows:

1. Plaintiffs' incorporate introductory paragraphs 1-77 as fully set forth above.

2. On October 16, 2015, SUSAN O'MARA, provided the LifeVest to SAMANTHA PARKER at RENAISSANCE AT MIDWAY.

3. At that time SUSAN O'MARA was a ZOLL Patient Services Representative, was an employee of ZOLL, was compensated by ZOLL, was acting as an agent of ZOLL.

4. SUSAN O'MARA had SAMANTHA PARKER sign a contract with ZOLL.

5. The contract obligated SAMANTHA PARKER to pay for the services provided by ZOLL and to use the LifeVest.

6. SUSAN O'MARA, ZOLL's agent, signed the same contract.

7. In connection with promoting and convincing physicians to prescribe and patients to use its LifeVest devices, ZOLL makes Marketing Statements on its website and directly to physicians and patients.

8. The Marketing Statements expressly warrants that:

a. patients may "return to their activities of daily living, while having the peace of mind that they are protected from SCA."
b. the LifeVest provides "constant monitoring, immediate protection, and offers peace of mind for patients."
c. "[i]f a life-threatening heart rhythm is detected, the device delivers a treatment shock to restore normal heart rhythm."

d. The entire event, "from detecting a life-threatening arrhythmia to automatically delivering a treatment shock, usually occurs in less than a minute."
e. The LifeVest "has a **98 percent first treatment shock success rate** for resuscitating patients from SCA."

9. ZOLL failed, among other things, to establish and maintain procedures for:

a. Analyzing processes, work operations, quality records, and other information to identify existing and potential causes of nonconforming product;
b. Investigating the cause of nonconformities;
c. Identifying appropriate actions needed to correct and prevent recurrence of nonconforming product;
d. Verifying and validating that the appropriate actions to prevent and remedy nonconformities were effective;
e. Documenting the processes and actions above.

10. As a result of ZOLL's failures, ZOLL could not know and did not know the success rate of the LifeVest, including whether the LifeVest did in fact have a 98 percent first treatment shock success rate.

11. ZOLL knew or should have known that warranties it made via the Marketing Statements were false and/or unsubstantiated when they were made.

12. SAMANTHA PARKER and/or her physicians justifiably relied on ZOLL's representations.

13. Had the SAMANTHA PARKER and her physicians known of the risks of the LifeVest and the lack of additional benefits, the plaintiff would not have relied upon the LifeVest to save her life.

14. SAMANTHA PARKER's death was the direct and proximate result of the LifeVest's failure comply with the warranties made by ZOLL via the Marketing Statements.

15. As a result of SAMANTHA PARKER's death, Plaintiffs have and continue to suffer damages, including but not limited to damages for (1) loss of support and services, (2) loss of companionship and protection, (3) mental suffering, (4) medical and funeral expense.

WHEREFORE, the Plaintiff, ANGELA PARKER, Special Administrator of the Estate of SAMANTHA PARKER, Deceased, demands judgment against the Defendant, ZOLL, in a dollar amount in excess of the jurisdictional limitation of this Court, and for such other and further amounts as the jury and the Court shall deem proper, plus the cost of this suit.

Respectfully submitted,
GOLDBERG & GOLDBERG

By: 
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